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TITLE: Framework for Smart Electronic Health Record- Linked Predictive Models to Optimize Care for Complex Digestive Diseases

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14. ABSTRACT

Our objective is to utilize de identified database constructed from the world-wide Military Electronic medical record for datasets (constructed for clinical purposes and not research) specific to patients with Crohn's disease (CD) and acute pancreatitis (AP). Using the collected data we will develop Bayesian Network (BN) models to predict outcomes in CD and AP (death, surgeries, hospitalizations, etc). Once our model is developed we hope to apply our model at an outside institution, specifically University of Pittsburgh Medical Center (UPMC) who will be conducting a similar experiment, testing our model on their EMR.

15. SUBJECT TERMS

16. SECURITY CLASSIFICATION OF:			**17. LIMITATION OF ABSTRACT**	**18. NUMBER OF PAGES**	**19a. NAME OF RESPONSIBLE PERSON**
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1. INTRODUCTION:

Complex disorders result from the interaction of genetic, metabolic and environmental factors that may not produce disease themselves but combine to alter disease severity and its progression. These factors, which may be contained as relevant data in an EMR can be used to build predictive models with the hope of improving disease management.

It is difficult to find these factors in EMR systems as the information is both structured and unstructured formats that have been collected over many years. Research studies in contrast only collect a limited snapshot of a patient's clinical history. This information is usually not rich enough to develop predictive models. To construct a useful patient profile requires collecting disease progression and treatment information from a wide variety of sources that may span a decade or more.

The University of Pittsburgh Medical Center (UPMC) has developed the Megascope application to provide a software platform for the integration of clinical, genomic and research data collected from multiple sources. The DoD, through its AHLTA, Essentris and CHCS electronic medical records and informatics systems has a worldwide data set of active duty, dependant and retired enrollees that is maintained in the Medical Records Data Repository.

Our study goal is to search our world-wide military medical record for datasets to develop Bayesian Network (BN) models to predict defined outcomes in CD and AP (death, surgeries, hospitalizations, etc.) Once our model is developed, we hope to apply the model to de-identified data set from the University of Pittsburgh, and also validate and test their Megascope model on our de-identified database.

The University of Pittsburgh's Department of Biomedical Informatics (DBMI), Division of Gastroenterology and Walter Reed National Military Medical Center (WRNMMC) Division of Gastroenterology, is an ideal collaboration to achieve this goal given their history of successful development of informatics applications and our clinical research in complex GI diseases and facility with the DoD electronic medical records systems.

2. OVERALL PROJECT SUMMARY:

As this study is a complex collaboration of partners inside and outside the DoD with unique expertise in their respective areas we will summarize the work in the past year by identifying work done by UPMC, WRNMMC, and the main DoD subcontractor Kennell and Associates. A s a collaborative effort, much of this work is over lapping and the summaries may be redundant in some respects where some or all parties are working on similar or identical problems.

WRNMMC: During the past year we have spent the majority of time working on the AP data set. With our contracting agency, Kennel and Associates we defined AP case definitions, refined and organized the data set from the world-wide military database into a workable format for data software and statistical analysis. Beyond setting case definitions for AP we also set specific variables for extraction from the EMR (i.e. demographics, hospitalization, medication, ICU stay, and death) that might best allow for analysis of factors which can inform a clinician regarding outcomes with these chronic diseases. Further, we set these cases with de-identified data against a published hierarchical method of identifying the primary etiology for AP. In this way we were able to compare or extracted data against previous published outcomes in AP and CP. This served as useful validation of our data set before entering the Bayesian Network phase for this data set, which we are set to complete by NOV 2013.

A major focus of the data analysis in AP has been to use a previously published method (Frey et al, Pancreas 2006) of hierarchical assignment of admitting etiology for each index case of AP. Thus using the index hospitalization, which presumably is an easily searchable event in any EMR one could better

characterize the cohort at initial admission then create models based on re-admissions, other risk factors etc in predicting long term morbidity like recurrent AP, surgery, ERCP, chronic pancreatititis and mortality.

For CD we have followed a similar working plan and have set case definitions and clinical variables for data extraction. We are working to set up a subcontract to UPMC for help in validating a text concepts method of extracting data using pathology reports as a standard for establishing outcomes in CD. Kennell and associates are currently working on the data extraction and assisting with the SOW and data sharing agreement with UPMC. Initial de-identified data for statistical analysis should be ready for initial experiments in DEC 2013 and text concepts supported outcome measurements ready for analysis and BN analysis by May 2013.

Due to the delays in starting this research a no-cost extension for 1JUL 2013-29 JUN 2014 was sought and approved, see attached letter.

Collaboration with Kennell and Associates: Kennell and Associates performed all data extraction from the MDR and ensured the transmission of de-identified, secure data to Walter Reed research team. Specifically, the following tasks were performed by Kennell and Associates to meet the objectives.

- Task 1 - Data use agreement with the TMA Privacy and Civil Liberties Office (PCLO) to obtain access to the necessary data files
- Task 2 - Developed functional specifications for analytic data files based on the case definitions and search parameters established by Dr. Betteridge and his team
- Task 3 - Write programming code
- Task 4 - Run programming code and conduct quality
- Task 5 - Where necessary, extract and evaluate text files and interpret text concepts to be included in the analytic data files
- Task 6 - Prepare data dictionary and any additional data documentation
- Task 7 - Assisted in the writing of any final reports or publications required for the study
- Task 8 - Attended annual project meetings with UPMC research team in Pittsburgh, PA
- Task 9 - Attended monthly project status meetings with Dr. Betteridge and his research team at WRNMMC
- UPMC subcontracts and collaborates with WRNMMC Research Team and Kennell and Associates to interpret text concepts and apply Megascope to the MHS electronic health records of the study cohort.

For Acute Pancreatitis, initial data extraction showed that Acute Pancreatitis accounts for around 7,000 hospitalizations to direct care DoD facilities of MHS beneficiaries annually. In identifying the AP cohort a unit of analysis was the AP admission to direct care Military Treatment Facilities (MTF) including Ft. Carson, Ft. Gordon, Tripler, Ft. Campbell, Walter Reed, Bethesda, Ft. Bragg, Ft. Bliss, Ft. Hood, Ft. Belvoir Community Hospital, Madigan, Landstuhl, Travis AFB, San Diego, NH Jacksonville, NH Pensacola, Camp Lejeune, Wright Patterson, Ft. Sam Houston, Lackland, Portsmouth. Utilizing ICD 9 codes (ICD9-9-CM-577.0) a data cohort was identified (see below).

Number of Acute Pancreatitis Admissions						
	FY 2009	FY 2010	FY 2011	FY 2012	FY 2013	Total
ALL AP Admissions (Direct Care)	835	799	776	857	153	**3428**
AP Prime Admissions	551	528	544	611	110	**2350**
AP 65+ Admissions	155	147	121	130	23	**578**

During analysis we found the military data set very similar to previously published regional cohorts for AP, except that our DoD data set at direct care MTF were significantly younger (see below). This likely reflects a limitation in searching the MDS for usable data which we have encountered with this project. Care received by Tricare beneficiaries "on the economy" is common. This is traceable by the Tricare claims data, however usable clinical data in generating predictive models requires access to laboratories, and radiographic studies, pharmacy records, even clinical notes. For this reason we limited our cohort to direct care MTF as above, which in turn likely gave us a younger cohort that is not reflective of the entire Tricare population.

Age Group	All AP Admissions (Direct Care)	AP Prime Enrolled Admissions	AP 65+ Admissions
0-17	84	78	
18-24	340	244	
25-34	597	487	
35-44	584	501	
45-64	1245	1032	
65+	578	8	578
TOTAL	**3428**	**2350**	**578**

Following creation of the research cohort we successfully applied a computer program written by Kennell team members to create a computer based algorithmic model for assigning each index case of AP an etiology for admission. This allowed for comparison not only based on demographic data and clinical parameters but a more detailed analysis by disease etiology over time when also applied to recurrent cases.

Etiology	Description	AP Admissions (Direct Care)	Percentage of all AP Admissions (Direct Care)
Group 1	**Pancreatic Cancer**	**46**	**1%**
Group 2	**Systemic Rheumatic Disease**	**68**	**2%**
Group 3	**ERCP**	**163**	**5%**
Group 4	**Biliary & Alcohol**	**88**	**2%**
Group 5	**Only Biliary**	**856**	**24%**
Group 6	**Only Alcohol**	**687**	**19%**
Group 7	**Hypertriglycerides**	**658**	**18%**
Group 8	**MS-DRGs, abdominal surgery**	**9**	**0%**
Group 9	**Miscellaneous**	**988**	**28%**

Data extraction for Crohns disease began in Summer 2013. Similar to AP, Kennell and associates created a data set from patients receiving care at direct care MTFs using the following algorithm:

Unit of Analysis: Patient (identified at initial CD diagnosis)

Qualifiers for Cohort:
Two ICD-9-CM Diagnosis Codes (555.0-555.9) within 1 year
One Diagnosis Code and prescription within 6 months
Three Diagnosis Codes within 1.5 years

Clean Period: 2 yrs. (prior to first diagnosis)
Follow up Period: 3 yrs. First diagnosis in FY 2009 or 2010.s.

MHS Wide		
Number of patients	**FY 2009**	**FY 2010**
Crohn's diagnosis (all-listed)	17,822	18,826
Qualified for Cohort	1,190	1,125
Percentage	6.7%	6%

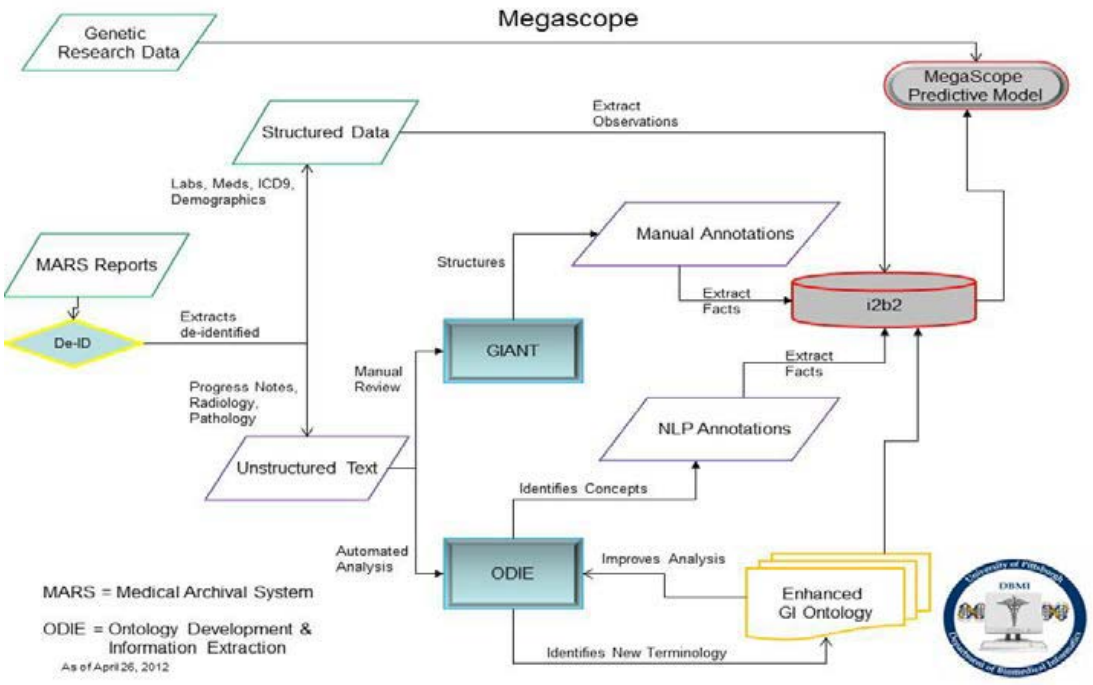
Direct Care Only		
Number of patients	**FY 2009**	**FY 2010**
Crohn's diagnosis (all-listed)	4,467	4,522
Qualified for Cohort	555	516
Percentage	12.4%	11.4%

With these defined cases we are currently working on identifying disease predictors which may predict things like intestinal surgery, requirement of ostomy, disability. Potential predictors include age, race labs. Charlson Comorbidity Index, history of fistula, cancer, etc, disease location descriptors, Lupus, Thyroid disease, Rheumatoid arthritis, history of Appendectomy, psoriasis.

The Crohn's work is also unique in that we are relying on our ability through our collaboration with UPMC to design and implement text reading software for validated NLM text concepts that will be extracted from the EMR physician notes like radiology reports or pathology reports. This work will validate our predictive models and hopefully open up a new pathway that other DoD researchers can use similar digital data extraction methods in a host of other diseases.

Work in Collaboration with UPMC:

Our work and meetings with University of Pittsburgh Medical Center has focused around development of variables for algorithmic analysis for the application of Baysian Network analysis. We have learned that the digital data sources we are using contain important clinical data in vastly different formats. UPMC has used their experience with Megascope (See figure below) to consult and guide the creation of workable data extraction programs applicable to DoD digital repository. In the second goal of creating the data cohorts themselves for AP and CD we are working to subcontract directly to UPMC.



The main thrust of our collaboration with UPMC in development of algorithmic variables for the IBD Cohort: UPMC identified the specific outcome of surgery for their Crohn's set by processing the operative reports through their "phenotyping pipeline". During our meeting with UPMC colleagues, we alerted them that the operative notes are not searchable in the Army cohort and we needed to modify our approach to identifying surgical events. Our revised approach is to identify a surgical outcome via a surgical pathology report since pathology reports are available on the military cohort. We plan on analyzing the pathology report data on the Pittsburgh cohort to see if we can obtain comparable results of positive operative note for surgery to positive pathology report for surgery. After the appropriate paperwork has been completed, Pitt will use UPMC phenotyped cohort on the military surgical pathology reports.

UPMC has developed a mature method for data extraction and disease characterization or "phenotyping" called GIANT, a web-based annotation tool enables researchers to annotate de-identified clinical reports. The application design focuses on providing users with an intelligent workspace, by displaying annotation forms and de-identified reports with the same view, automatic report queuing and providing easy access to annotation guidelines and data definitions. The application produces user statistics to report agreement between multiple annotators who are reviewing the same report. This tool was built using the Django (www.djangoproject.com) web framework, which is an open-source project built on the Python (www.python.org) programming language. The annotation tool features include controlled user access, database support, progress reporting, task-specific error checking and a site administration interface. There are two output streams for GIANT. The first output is the report annotations completed by the clinical expert that will be imported into i2b2. The second output is the list of concepts identified in ODIE that appear most frequently in documents. This concept generator is used for feature selection to comprise the elements in the predictive model.

In order to search and derive variables from free text electronic sources like pathology reports, radiology or endoscopy reports a reliable system of ontology processing is required. UPMC is experienced in this area as well and will be consulting on developing the CD variables from free text pathology and possibly radiology reports. In their experience with GI surgeries for CD they found that GI surgery domain is not well represented in standard ontologies. So, they are adding each of the procedure terms to our ontology and will contribute this ontology to the National Center for Biomedical Ontology (www.bioontology.org) upon completion. The same condition exists with identifying acute pancreatitis (AP) in radiology reports. We are continuing our work with UPMC in development of specific ontology applicable to pathology and radiology reports within the DoD data sources. Since ODIE identifies both concepts (CUI) and semantic types (TUI) found in the narrative reports. These data will be used as the input for clinical variables in building the prediction models.

3. **KEY RESEARCH ACCOMPLISHMENTS:** Application of algorithmic computer assignment of etiology for cases of AP to a worldwide electronic medical record. This had previously only been accomplished at a single center or smaller regional network.

   Development of computer code and multisource software platform in collaboration with Kenell and UPMC to allow for extraction of important clinical variables from a digital data repository owned by the DoD utilizing existing data and through modifications to new technologies (GIANT, MEGASCOPE). To my knowledge we are the first group to begin developing working tools for this type of large data cohort development which we intend to then process through algorithmic analysis with Baysian network analysis identifying possible clinical predictors of severe phenotyopes in chronic GI diseases and at the same time validating our methods for use again in other chronic illness.

4. **CONCLUSION:** Successful data extraction with preset specific case definitions and outcomes based results is establishing a model for utilizing our worldwide military clinical EMR as an effective tool for future research, resource allocation and planning with regard to complex chronic illnesses. With our planned application of BN analysis to this robust data set we hope to establish an example of how clinical researchers can use the clinical data collected in EMR to provide answers to important clinical questions and empower military physicians to make better management decisions in caring for our military beneficiaries.

5. **Reportable outcomes:** See attached 2013 Progress Timeline (appendix)

6. **PUBLICATIONS, ABSTRACTS, AND PRESENTATIONS: (2 Abstracts, see appendix)**

   Scott E Cunningham, MD, John D Betteridge MD, Corrine Maydonovich BS, Ganesh R Veerappan, MD. *The Epidemiology of Acute Pancreatitis within a Nationwide Military Population.* Digestive Disease Week, Orlando FL. May 2013

   Scott E Cunningham, MD, Corrine Maydonovitch BS, Ganesh R Veerappan MD, John D Betteridge MD. *The Epidemiology and Outcomes of Acute Pancreatitis Admissionswithin a Nationwide Military Population.* American College of Gastroenetrology, San Diego CA. OCT 2013

7. **APPENDICES:**
   No cost extension approval from WRNMMC IRB
   Project Timeline
   DDW 2013 Abstract
   ACG 2013 Abstract

WALTER REED NATIONAL MILITARY MEDICAL CENTER
OFFICE OF THE COMMANDER
8901 WISCONSIN AVENUE
BETHESDA MARYLAND 20889-5600

Date: May 8, 2013

From: WRNMMC DRP Determinations
To: MAJ John Betteridge, MC, USA

Subj: WRNMMC DRP Determinations REVIEW OF 366706-4

PROJECT TITLE:	[366706-4] The Use of Electronic Medical Record to Generate Bayesian Networks to Predict Patient Outcome in Patients with Crohn's Disease and Acute Pancreatitis
REFERENCE #:	
SUBMISSION TYPE:	Amendment/Modification
ACTION:	Amendment for Exempt Protocol
DECISION DATE:	

1. Thank you for your amendment submission for this research study. The WRNMMC DRP Determinations has determined this project is EXEMPT FROM IRB REVIEW according to federal regulations in category 32 CFR 219.101.(b)(4), in that it involves the secondary analysis of pre-existing, de-identified data. This amendment changed the Principle Investigator (PI) to you and also contained an extension on the period of performance for your funding to do this research. You may continue your project and begin functioning as the PI upon receipt of this letter.

2. When you complete your research you must file a closure report.

3. Your request for HIPAA authorization waiver has been reviewed and approved IAW 45 CFR 164.

4. Any presentations or publications that arise from this project must go through appropriate publications clearance review.

5. Any changes to this protocol must be reviewed by this office to ensure the regulatory status of your protocol does not change.

6. If you have any questions, the POC is Janine Danko at 301-295-8279 or janine.danko@health.mil. Please include your project title and reference number in all correspondence with this committee.

This document has been electronically signed in accordance with all applicable regulations, and a copy is retained within our records.

Project Timetable

TASK	Y1Q1	Y1Q2	Y1Q3	Y1Q4	Y2Q1	Y2Q2	Y2Q3	Y2Q4	Y3Q1	Y3Q2	Y3Q3	Y3Q4	Status
HMJF Contract with Kennell, Maydonovitch (Task 1)	X												Complete
IRB Protocol (Task 1)		X											Complete
Scientific Rev Committee (Task 1)			X										Complete
Protocol Approval (Task 1)				X									Complete
Secondary Approval at MRMC-HRPO (Task 1)				X									Complete
TMA Approval at Kennell and Associates (Task 1)				X									Complete
Meeting at Univ Pittsburg (Task 1)				X									Complete
Kennell; data extraction, AP cohort					X	X							Complete
Kennell creates a data set for AP patients							X	X					Complete
PROJECT EXTENTION								X					Complete
Bayesian Model for AP at WR									X				**On Schedule**
Establish definitions for CD / extraction									X	X	X		On Schedule
Kennell creates CD data set											X		On Schedule
CD BN at WR												X	On Schedule
Compare BN Models at WR and U Pitt												X	On Schedule
Meeting at UPMC											X		On Schedule
AP Manuscript										X			2014
CD Manuscript												X	2014

Green box = completed; yellow box = on schedule; CD= Crohn's disease; AP=acute pancreatitis; BN= Bayesian Network
WR= Walter Reed; U Pitt= University of Pittsburgh

THE EPIDEMIOLOGY OF ACUTE PANCREATITIS WITHIN A NATIONWIDE MILITARY POPULATION

Scott Cunningham, MD, Corrine Maydonovich, BS, Ganesh Veerappan, MD, John Betteridge, MD,

Walter Reed National Military Medical Center, Bethesda MD

Purpose:

The aim of this study is to examine the epidemiology of acute pancreatitis (AP) in our military health care system, and explore the demographic risk factors for the various etiologic subtypes of AP.

Methods:

Using the electronic medical records (EMR) and healthcare claims databases under the Military Healthcare System Data Repository (MDR), the total number of admissions, laboratory data and clinical outcomes related to acute pancreatitis (ICD9-CM 577.0) were examined from October 1, 2008 to September 30, 2012. A hierarchical methodology of assigning an etiology to each case of acute pancreatitis was employed, with the hypothesis that this method yields more specific classification of acute pancreatitis subtypes.

Results:

Over this 4-year period 2,927 cases of AP were identified in a study population of 2,973,523 patients. The cumulative incidence of AP was 25 per 100,000 patients per year. Patients with AP had a mean age of 47±19 years, 52% male, and 52% Caucasian. Incidence rates were similar among genders (male to female, RR 0.96) and races (Caucasian to African Americans, RR 1.12). The overall mortality rate was 0.6%. Six percent of patients had severe AP as defined by an ICU stay of >48 hours. Idiopathic pancreatitis was the most common single cause of AP (45%), followed by gallstone pancreatitis (27%). Alcohol accounted for 16% of the cases of AP. Blacks were nearly twice as likely as whites to have alcohol as the cause of pancreatitis (OR 1.92). Whites were nearly twice as likely as blacks to have gallstones as the cause of their pancreatitis (OR 1.81). Females were significantly more likely to have biliary pancreatitis than males (OR 1.98). Males were significantly more likely to have alcoholic pancreatitis (OR 3.28). The severity of pancreatitis did not differ significantly among different etiologies. Alcohol was the most common cause of recurrent pancreatitis, ranging from 40% of the second admissions; to more than 80% of 6^{th}, 7^{th}, and 8^{th} admissions.

Conclusions:

Our study provides an assessment of the burden of AP within a diverse, nationwide population. A hierarchical method in such a vast EMR reliably allows an accurate assignment of etiology. Our mortality rate was significantly lower, possibly due to our relatively younger and healthier population. Overall incidence rates of AP were similar between the sexes and between Caucasians and African Americans. However, this study proves that significant differences exist in the subtypes of AP between demographic groups. This data might allow a more focused diagnostic workup at onset while still identifying early, those at highest risk for recurrence.

The Epidemiology of Acute Pancreatitis within a Nationwide Military Population

Scott Cunningham, Corrine Maydonovich, Ganesh Veerappan

Walter Reed National Military Medical Center

Introduction:

Acute pancreatitis (AP) is a commonly encountered gastrointestinal illness, with a broad clinical spectrum, ranging in severity from mild to life-threatening. Due to this clinical heterogeneity, it is important to identify high risk patients at presentation to improve patient care while optimizing clinical resources. Numerous population-based studies describe demographic data, in an attempt to identify risk factors that predispose to acute pancreatitis. Scoring systems have developed based on various clinical, radiological and laboratory data with reasonable success.

Aim:

The aim of this study is to examine the epidemiology of acute pancreatitis in our military health care system, and explore demographic and laboratory factors associated with a more severe course of pancreatitis.

Methods:

Using the electronic medical records and healthcare claims databases under the Military Healthcare System Data Repository (MDR), the total number of admissions and outcomes related to acute pancreatitis (ICD9-CM 577.0) were examined over a period from October 1, 2008 to September 30, 2012. Data extracted for this analysis included demographic (age, gender, race, body mass index) and specified laboratory data that may be predictive of severe pancreatitis. For analysis, lab values were dichotomized based on prior scoring systems to predict severity (Creatinine > 2.0 mg/dL, white blood cell count (WBC) > 16,000 cells/µL, glucose > 200 mg/dL, lactate dehydrogenase (LDH) > 350 IU/L, aspartate aminotransferase (AST) > 250 IU/L, calcium < 8 mg/dL, hematocrit 44%, blood urea nitrogen (BUN) >25 mg/dL). Outcomes included mortality, ICU admission > 48 hours, and evidence of end organ damage. Severe pancreatitis was defined as an ICU admission > 48 hours. Logistic regression was performed to identify independent factors associated with severe pancreatitis.

Results:

Over this 4 year period, 2,197 cases of acute pancreatitis were identified in a study population of 536,929 patients. Patients with acute pancreatitis had a mean age of 41y$\pm$14, 49% male, and 53% Caucasian. The cumulative incidence of AP was 1.0 per 1000 patients per year. Acute pancreatitis consisted of 0.4% of all hospitalizations over this period. Incidence rates were similar among genders (male 1.04/1000, female 1.01/1000) and races (Caucasians 2.33/1000, African Americans 2.13/1000). The overall mortality rate was 0.2%. Five percent (107/2,197) of patients had severe pancreatitis.

Independent predictors of severe pancreatitis include age > 55 (OR, 1.6; P< 0.04), male gender (OR, 1.5; P<0.05), white blood cell count >16,000 cells/mm^3 (OR, 2.7; P <0.01), serum glucose >200 mg/dL (OR, 2.1; P<0.02) and serum calcium <8 mg/dL (OR, 6.3; P<0.01).

Conclusions:

Compared to other recent population-based epidemiologic studies, we report a higher incidence of AP (1.0 vs. 0.6 per 1,000), less severe pancreatitis (5% severity) and lower mortality (0.2%). Independent predictors of severe pancreatitis include age >55, male gender, elevated wbc, elevated glucose and decreased serum calcium, which have been validated in other studies.